

# Exhibit 3

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

Barbe Puro, on behalf of herself and all  
others similarly situated,

Plaintiffs,

v.

New England Compounding Pharmacy,  
Inc., d/b/a New England Compounding  
Center,

Defendant.

No. 12-cv-02605 (DWF/SER)

**DEFENDANT NEW ENGLAND  
COMPOUNDING PHARMACY, INC.,  
D/B/A NEW ENGLAND  
COMPOUNDING CENTER'S  
ANSWER**

**JURY TRIAL DEMANDED**

Defendant, NEW ENGLAND COMPOUNDING PHARMACY, INC. d/b/a New England Compounding Center (“NECC”) by and through its undersigned counsel, hereby answers Plaintiffs’ Complaint as follows:

1. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 1.
2. Defendant admits that it compounded and dispensed a preparation known as methylprednisolone acetate (“MPA”). Defendant is not required to respond to the remaining allegations of Paragraph 2 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
3. Defendant is not required to respond to the allegations of Paragraph 3 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.

4. Defendant is not required to respond to the allegations of Paragraph 4 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

5. Defendant admits that it voluntarily recalled certain of its compounded and dispensed preparations. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 5.

6. Defendant states that the CDC's statements speak for themselves, but to the extent a responsive pleading is necessary, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 6.

7. Defendant states that the CDC's statements speak for themselves, but to the extent a responsive pleading is necessary, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 7 and therefore denies the same.

8. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 8.

9. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 9.

10. Defendant admits that it compounded and dispensed certain preparations, including MPA. Defendant is not required to respond to the remaining allegations of Paragraph 10 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

11. Defendant admits that it is a Massachusetts corporation with a principal place of business located at 697 Waverly Street, Framingham, Massachusetts.

12. Defendant is not required to respond to the allegations of Paragraph 12 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.

13. Defendant is not required to respond to the allegations of Paragraph 13 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.

14. Defendant admits that, from time to time, it has in the past compounded and dispensed preparations in Minnesota. Defendant is not required to respond to the remaining allegations of Paragraph 14 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.

#### **RESPONDING TO FACTUAL BACKGROUND**

15. Defendant admits that it compounded and dispensed certain preparations, but denies the remaining allegations in Paragraph 15.

16. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 16.

17. Defendant admits that it compounded and dispensed MPA from its Massachusetts facility. Defendant is not required to respond to the remaining allegations

of Paragraph 17 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.

18. Defendant admits that it voluntarily recalled certain of its compounded and dispensed preparations. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 18.

19. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 19

20. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 20.

21. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 21.

22. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 22.

23. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 23.

24. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 24.

25. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 25.

26. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 26.

27. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 27.

28. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 28.

29. Defendant is not required to respond to the allegations of Paragraph 29 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

30. Defendant is not required to respond to the allegations of Paragraph 30 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations.

31. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 31.

32. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 32.

33. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 33.

34. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 34.

#### **RESPONDING TO CLASS PREREQUISITE ALLEGATIONS**

35. Defendant denies the allegations in Paragraph 35.

36. Defendant denies the allegations in Paragraph 36.

37. Defendant denies the allegations in Paragraph 37.

38. Defendant denies the allegations in Paragraph 38.

39. Defendant denies the allegations in Paragraph 39.

40. Defendant denies the allegations in Paragraph 40.

41. Defendant denies the allegations in Paragraph 41.

42. Defendant denies the allegations in Paragraph 42.

43. Defendant denies the allegations in Paragraph 43.

44. Defendant denies the allegations in Paragraph 44.

#### **ANSWERING COUNT I**

45. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

46. Defendant admits that it compounded and dispensed a preparation known as MPA. Defendant is not required to respond to the remaining allegations of Paragraph 46 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

47. Defendant is not required to respond to the allegations of Paragraph 47 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

48. Defendant is not required to respond to the allegations of Paragraph 48 that set forth legal duties. However, to the extent such allegations may be construed against Defendant, they are denied.

49. Defendant is not required to respond to the allegations of Paragraph 49 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

50. Defendant is not required to respond to the allegations of Paragraph 50 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

51. Defendant is not required to respond to the allegations of Paragraph 51 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

52. Defendant is not required to respond to the allegations of Paragraph 52 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

53. Defendant is not required to respond to the allegations of Paragraph 53 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

### **ANSWERING COUNT II**

54. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

55. Defendant is not required to respond to the allegations of Paragraph 55 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.



56. Defendant is not required to respond to the allegations of Paragraph 56 that set forth legal duties or legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

57. Defendant is not required to respond to the allegations of Paragraph 57 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

58. Defendant is not required to respond to the allegations of Paragraph 58 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

59. Defendant is not required to respond to the allegations of Paragraph 59 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

#### **RESPONDING TO PRAYER FOR RELIEF**

Defendant denies entitlement to the relief requested in the Complaint.

#### **JURY DEMAND**

Defendant demands a trial by jury.

#### **DEFENSES AND AFFIRMATIVE DEFENSES**

During the course of litigation, a number of defenses and/or affirmative defenses may become available to this or any Defendant. To the extent any of the following are available and may apply, notice is hereby given of the following:

1. The Complaint fails to state a claim or cause of action, cognizable in law or equity.

2. The Complaint fails to allege a cognizable claim for breach of any applicable standard for the practice of pharmacy.

3. Standing to sue may be lacking on all or some of the claims.

4. This action may be dismissed and/or transferred under the doctrine of *forum non conveniens*.

5. No injury has been sufficiently stated or proven.

6. The Complaint fails to sufficiently identify a preparation compounded or dispensed by any defendant.

7. The alleged injuries or damages may not have been proximately caused by any defendant.

8. The alleged injuries or damages may have been proximately caused by one or more unforeseeable, independent intervening or superseding events beyond the control of and unrelated to the conduct of any defendant.

9. The injuries or damages alleged may have been caused or contributed to by pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses.

10. The injuries or damages alleged may have been caused or contributed to by an idiosyncratic reaction to any compounded or dispensed preparation.

11. The preparation alleged to have caused injury or damage was dispensed and compounded in accordance and consistent with the state of the art and with all applicable federal and/or state standards for the dispensing and compounding of similar preparations.

12. All preparations dispensed were formulated, designed, tested, compounded, processed, sterilized, distributed, labeled and sold in compliance with the provisions of all applicable federal and/or state law, rules and/or other regulations.

13. The alleged injuries or damages may have been caused or contributed to by known risks inherent in certain medical procedures, and which are otherwise open and obvious, or that were voluntarily undertaken, with full knowledge and consent. Such risks were therefore assumed and accepted through consenting and engaging in said medical procedures.

14. Adequate warnings and information were available to the medical profession, including any prescribing or administering healthcare provider.

15. The preparations compounded and dispensed were intended to be used and administered only by licensed health care practitioners in the care and treatment of their patients. Such licensed health care practitioners were knowledgeable, learned intermediaries and sophisticated users in treating patients and performing medical procedures.

16. The alleged injuries or damages were caused by the unforeseeable misuse, abuse, or inappropriate handling of the preparation by others, which was unforeseeable to any defendant.

17. The preparation may have been modified, altered or changed from the condition in which it was originally compounded and dispensed, which modification, alteration or change caused or contributed to the alleged injuries or damages.

18. The federal government has totally or partially preempted the field of law applicable to compounded preparations. The laws of any state purporting to set forth different or contrary duties are preempted in whole or in part.

19. Claims under applicable state law fail to state any claim upon which relief can be granted in that such claims for relief, if granted, would conflict with and would impede, impair, frustrate or burden the effectiveness of federal law and would violate the Supremacy Clause (Art. VI., §2) of the United States Constitution.

20. It is impossible for any defendant to have complied with the purported duties imposed by both federal and state law.

21. To the extent that comments (g), (h), (i), (j) and (k) of Section 402A of the Restatement (Second) of Torts and Comment (b) of Section 6 of the Restatement (Third) of Torts are applicable, such provisions may be relied upon in defense of this action.

22. Damages, if any, have not been appropriately mitigated.

23. The injuries or damages alleged may have been caused in whole or in part by the contributory negligence and/or culpable conduct of others and not as a result of any conduct on the part of any defendant. Recovery, if any, should be limited or reduced in proportion to the parties' comparative fault and in accordance with applicable state law.

24. The liability of any defendant is limited to the allowable percentage of culpability found and should be further limited by virtue of the fault of other parties or entities (appearing and non-appearing, named and un-named) and in accordance with applicable state law.

25. The injuries or damages alleged may be attributable to several causes and, accordingly, should be apportioned among the various causes according to the respective contribution of each cause of the harm sustained, if any.

26. The claim should be diminished in whole or in part by any amount paid or fairly allocable to any party that has settled or may settle.

27. Any verdict or judgment must be reduced by those amounts which have or will, with reasonable certainty, replace or indemnify, in whole or in part, for any past or future claimed loss, including from any collateral sources such as insurance, disability, social security, worker's compensation or employee benefit programs.

28. Liability for non-economic loss is limited in accordance with the relative culpability of all persons or entities contributing to the total liability for non-economic loss, including named parties and others over whom personal jurisdiction could have been obtained with due diligence.

29. The claims are barred, in whole or in part, based upon a balancing of risk and utility factors.

30. The alleged damages were not caused by any failure to warn.

31. Plaintiff has failed to comply with the requirements of Minnesota Statute § 145.682 to provide an expert affidavit.

32. Defendant denies all allegations not expressly admitted and specifically reserves all affirmative or other defenses that it may have against the purported class. It is not necessary at this time for NECC to delineate such defenses against the purported

class because no class has been certified and the putative class members are not parties to this litigation.

33. The claims of some members of the purported class are barred because they never suffered the alleged injury.

34. The allegations of the Complaint do not adequately set forth the elements required to proceed with a representative action under applicable state and/or federal laws. The putative class representatives have thus failed to state a claim upon which they or any other purported class member could proceed.

35. The Complaint does not provide a legally sufficient or sustainable class definition.

36. The allegations of the Complaint do not satisfy the prerequisite of numerosity.

37. The allegations of the Complaint do not satisfy the prerequisite of ascertainability.

38. The allegations of the Complaint do not satisfy the prerequisite of commonality.

39. The allegations of the Complaint do not satisfy the prerequisite of typicality.

40. The allegations of the Complaint do not satisfy the prerequisite of adequacy.

41. The allegations of the Complaint do not satisfy the prerequisite of superiority.

42. Other defenses may be relied upon, including any that may be asserted by others, or that may become available or apparent during proceedings in this case. The right to amend and incorporate such defenses is hereby reserved.

WHEREFORE, Defendants demand Judgment of this Court:

- a. dismissing the Complaint against it, with prejudice;
- b. awarding to Defendant the costs, expenses, and fees associated with defending this action; and
- c. granting such other and further relief, both legal and equitable, that the Court deems just and proper.

Dated: November 19, 2012

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/s/ Molly J. Given

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